

CLAIMS

1. A method for treating or preventing an epithelial lesion in a mammal comprising administering a trefoil domain-containing polypeptide (TDCP) or a trefoil peptide fragment.
2. The method of claim 1, wherein said TDCP or said trefoil peptide fragment is selected from a group consisting of hITF₂₅₋₆₂, hITF₂₂₋₆₂, hITF₂₁₋₆₂, hITF₂₅₋₇₀, hITF₂₂₋₇₀, hITF₂₁₋₇₀, hITF₂₅₋₇₂, hITF₂₂₋₇₂, hITF₂₁₋₇₂, hITF₂₅₋₇₃, hITF₂₂₋₇₃, hITF₂₁₋₇₃, and EA-hITF₁₅₋₇₃.
3. The method of claim 1, wherein said trefoil peptide fragment is ITF₁₅₋₇₃.
4. The method of claim 1, wherein said TDCP comprises ITF₁₅₋₇₃.
5. The method of claim 1, wherein said TDCP or said trefoil peptide fragment comprises a trefoil domain having an amino acid sequence substantially identical to any one of SEQ ID NOs: 3-5.
6. The method of claim 1, wherein said TDCP or said trefoil peptide fragment comprises a trefoil domain having an amino acid sequence substantially identical to SEQ ID NO: 6.
7. The method of claim 1, wherein said TDCP or said trefoil peptide fragment is administered as a homodimer or heterodimer.
8. The method of claim 1, wherein said epithelial lesion is a lesion of the upper alimentary canal.

9. The method of claim 8, wherein said epithelial lesion is, aphthous stomatitis, mucositis, gingivitis, a lesion of the esophagus, a lesion caused by gastro-esophageal reflux disease, or a lesion caused by Behcet's disease.

10. The method of claim 1, wherein said epithelial lesion is a lesion of the dermis or epidermis.

11. The method of claim 10, wherein said lesion is a traumatic lesion, a burn, a pressure ulcer, eczema, contact dermatitis, psoriasis, a herpetic lesion, or acne.

12. The method of claim 10, wherein said skin lesion is caused by a bacterial, viral, or fungal infection.

13. The method of claim 1, wherein said epithelial lesion is a lesion of the vaginal, cervical, or uterine epithelium.

14. The method of claim 13, wherein said skin lesion is caused by a bacterial, viral, or fungal infection.

15. The method of claim 1, wherein said epithelial lesion is a lesion of the epithelium of the gastrointestinal tract.

16. The method of claim 1, wherein said epithelial lesion is a lesion of the distal bowel.

17. The method of claim 16, wherein said lesion is enteritis, proctitis, or caused by Crohn's disease or ulcerative colitis.

18. The method of claim 1, wherein said epithelial lesion is a lesion of the respiratory epithelium.

19. The method of claim 18, wherein said lesion is caused by an allergic reaction, asthma, chronic obstructive pulmonary disease, or the inhalation of smoke, particulate matter, or a chemical.

20. The method of claim 1, wherein said epithelial lesion is a lesion the corneal epithelium.

21. The method of claim 20, wherein said lesion is a superficial punctate keratitis, a corneal ulcer, keratoconjunctivitis caused by herpes or adenovirus, phlyctenular keratoconjunctivitis, a keratoconus, a conjunctiva, a keratoconjunctivitis sicca (dry eyes), an ocular inflammation, a cicatricial penhigoid, a bacterial or protozoal infection.

22. The method of claim 1, wherein said lesion is caused by antineoplastic chemotherapy or antineoplastic radiation therapy.

23. A pharmaceutical composition comprising a trefoil domain-containing polypeptide (TDCP) or trefoil peptide fragment and a pharmaceutically acceptable carrier.

24. The composition of claim 23, wherein said TDCP or said trefoil peptide fragment is selected from a group consisting of hITF₂₅₋₆₂, hITF₂₂₋₆₂, hITF₂₁₋₆₂, hITF₂₅₋₇₀, hITF₂₂₋₇₀, hITF₂₁₋₇₀, hITF₂₅₋₇₂, hITF₂₂₋₇₂, hITF₂₁₋₇₂, hITF₂₅₋₇₃, hITF₂₂₋₇₃, hITF₂₁₋₇₃, and EA-ITF₁₅₋₇₃.

25. The pharmaceutical composition of claim 23, wherein said trefoil peptide fragment is ITF₁₅₋₇₃.

26. The pharmaceutical composition of claim 23, wherein said TDCP comprises ITF₁₅₋₇₃.

27. The pharmaceutical composition of claim 23, wherein said TDCP or said trefoil peptide fragment comprises a trefoil domain having an amino acid sequence substantially identical to any one of SEQ ID NOs: 3-5.

28. The pharmaceutical composition of claim 23, wherein said TDCP or said trefoil peptide fragment comprises a trefoil domain having an amino acid sequence substantially identical to SEQ ID NO: 6.

29. The pharmaceutical composition of claim 23, wherein said TDCP or said trefoil peptide fragment is homodimeric or heterodimeric.

30. The pharmaceutical composition of claim 23, wherein said composition is suitable for intravenous, intramuscular, or subcutaneous injection.

31. The pharmaceutical composition of claim 23, wherein said composition is formulated as an oral rinse, oral spray, or ingestible liquid.

32. The pharmaceutical composition of claim 23, wherein said composition is formulated as a suppository, enema, pessary, or a vaginal rinse.

33. The pharmaceutical composition of claim 23, wherein said composition is formulated for inhalation.

34. The pharmaceutical composition of claim 23, wherein said composition is formulated for administration to the eye.

35. The pharmaceutical composition of claim 23, wherein said composition further comprises a second therapeutic agent.

36. The pharmaceutical composition of claim 35, wherein said second therapeutic agent is an analgesic, an anti-viral agent, an antibacterial agent, an anti-fungal agent, an antiproliferative agent, an anti-inflammatory agent, or a steroid.

37. A method for producing hITF₂₁₋₇₂ or hITF₂₁₋₇₃ comprising providing a microorganism capable of expressing recombinant hITF₂₁₋₇₂ or recombinant hITF₂₁₋₇₃ and culturing said microorganism at about pH 5.0.

38. The method of claim 37, wherein said microorganism is a yeast.

39. The method of claim 38, wherein said yeast is *P. pastoris*.

40. A method for producing hITF₁₅₋₇₂ or hITF₁₅₋₇₃ comprising providing a microorganism capable of expressing recombinant hITF₁₅₋₇₂ or recombinant hITF₁₅₋₇₃ and culturing said microorganism at about pH 6.0 – pH 6.5.

41. The method of claim 40, wherein said microorganism is a yeast.

42. The method of claim 41, wherein said yeast is *P. pastoris*.